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Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: a feasibility trial with an embedded qualitative component

Submission date
04/09/2018

Recruitment status
No longer recruiting

Registration date
11/09/2018

Overall study status
Completed

Last Edited
21/07/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the UK 3.2 million working days are lost annually due to 30% of adults experiencing low back pain at any one time. 20% of individuals with low back pain seek care from their GP, representing 7% of all GP consultations. Early assessment and management of low back pain is important to reduce long-term pain and disability. Currently, there are too few GPs to meet the demands of the British public, with numbers predicted to fall further by 2020. To help combat this shortage, a range of organisations including the British Medical Association and the Chartered Society of Physiotherapy have committed to enabling direct access to physiotherapists in their local health centre without having to see a GP first for problems such as low back pain. It is envisaged that Advanced Physiotherapy Practitioners (APPs) working in these roles will prescribe medicines such as painkillers as part of a holistic treatment strategy to get patients managing their back pain as quickly and as best as possible. Physiotherapist prescribing remains novel, with the first prescribers qualifying in 2013. The true benefits now need to be evaluated, to do this we need to complete a clinical trial. To ensure that we are able to complete a trial of worth, we are first completing a feasibility trial.

Who can participate?
Patients aged 18 and over with low back pain

What does the study involve?
As per current normal practice, an APP completes the initial assessment and physiotherapeutic treatment of participants as deemed appropriate (traditional role). In addition to the physiotherapist's traditional role, the APP can prescribe medicines independently. If advice about medication or prescription drugs are required/no longer required, these are prescribed /de-prescribed by the APP immediately, rather than referring the patient back to their GP for assessment for medications as per current normal practice. The medications provided should be taken by the patient as prescribed in the time frames discussed in the clinical consultation. Following initial assessment by a physiotherapist the participants are required to complete

online questionnaires at 6 and 12 weeks. The trial explores the measures used to assess outcomes from treatment by using questionnaires and small devices call accelerometers (like 'fitbits') which assess how active or still people are during the day. The trial also explores how patients and physiotherapists involved found taking part via focus groups and interviews.

What are the possible benefits and risks of participating?
It is anticipated that the results of this trial will be used to help design a full trial. The information participants provide may help them and other patients in the future. It will not change the treatment that they receive for their back pain. There are no anticipated risks associated with undertaking this study and the only cost to the participant(s) is the time involved with completing the questionnaire and (for some people) attending a focus group. Participation in this study is entirely voluntary. It is possible that when talking about a participants back pain or filling in the questionnaire participants may be asked to relive events which are emotional for them. However, every effort will be made to ensure that participants are comfortable at all times.

Where is the study run from?
1. Guys and St Thomas' NHS Foundation Trust (UK)
2. Windermere Health Centre & Ambleside Health Centre (UK)
3. Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2018 to December 2019

Who is funding the study?
1. Health Education England (UK)
2. Private Physiotherapy Education Fund (UK)

Who is the main contact?
Mr Timothy Noblet

Contact information

Type(s)
Public

Contact name
Mr Timothy Noblet

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number
250734

ClinicalTrials.gov number

Secondary identifying numbers
RG_18-101, IRAS 250734

Study information

Scientific Title
Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: a feasibility trial with an embedded qualitative component

Study objectives
Aim: To evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by advanced physiotherapy practitioners (APPs) for patients with LBP in primary care, to inform the design of a future definitive stepped-wedged cluster trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/10/2018, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 104 8124; NRESCommittee.London-WestLondon@nhs.net), ref: 18/LO/1793

Study design
The feasibility trial will utilise a mixed-methods research approach, comprising of:
1. A quantitative one-armed feasibility trial
2. Qualitative semi-structured interviews and patient focus groups, using thematic analysis

Primary study design
Interventional

Secondary study design
Feasibility trial with an embedded qualitative component

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Low back pain

Interventions
Randomisation will not occur in this feasibility trial as the aim is to test the methods etc. The feasibility trial will use the proposed experimental arm for the full study to test the feasibility of the methods, outcome measures, analysis and synthesis. The control arm of the definitive trial will be current normal practice. As per current normal practice, an APP acting as a FCP will complete the initial assessment and physiotherapeutic treatment of participants as deemed appropriate through evidence based clinical reasoning and best practice (traditional role). In addition to the physiotherapist's traditional role, the APP will have the competence and legal ability to prescribe medicines independently. If advice about medication or prescription drugs are required/no longer required within the multi-modal physiotherapeutic context, these will be prescribed/de-prescribed by the APP immediately, rather than referring the patient back to their GP for assessment for medications as per current normal practice. The medications provided should be taken by the patient as prescribed in the time frames discussed in the clinical consultation. Following initial assessment by a physiotherapist the participants will be required to complete online outcome measurement questionnaires at 6 and 12 weeks.

Intervention Type
Mixed

Primary outcome measure
Measured at 6 and 12 weeks:
1. Overall pain, measured using the Numerical Rating Scale (NRS)
2. Disability, assessed using the Roland Morris Disability Questionnaire (RMDQ)

Secondary outcome measures
Measured at 6 and 12 weeks:
1. Health-related quality of life, measured using EQ5D
2. Kinesiophobia, measured using the Tampa scale
3. Physical activity/sedentary behaviour, measured using accelerometers
4. Sleep, measured using accelerometers
5. Return to work (days)
6. Prescription utilisation (number of occasions)
7. Number of appointments with other healthcare professionals about this episode of LBP

Overall study start date
01/05/2018

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Male and female patients, aged >18 years
2. Non-specific LBP +/- leg pain requiring medication advice and drug prescription on assessment
3. Classified as Moderate risk using the STarT Back Tool (classified as potentially benefiting from medicines and active physiotherapy treatment)

4. Able to read/communicate in English (due to funding restrictions for interpreters and translators limited in the inclusion of participant speaking other languages)
5. Capable of following the demands inherent of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
29

Key exclusion criteria
1. Signs of lumbar nerve root compression
2. Red Flags including potential spinal fracture, inflammatory disease, infection or malignancy
3. Spinal stenosis
4. Suspicion of or confirmed corda equine syndrome
5. Does not have capacity to consent

Date of first enrolment
01/10/2018

Date of final enrolment
10/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guys and St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 9RT

Study participating centre
Windermere Health Centre & Ambleside Health Centre
Cumbria
United Kingdom
LA23 2EG

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S5 7AT

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston Park Road
Birmingham
England
United Kingdom
B15 3TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Education England

Funder Name

Results and Publications

Publication and dissemination plan

The dissemination strategy is multi-faceted in order to achieve maximum awareness and impact, and therefore potential change to NHS perceptions, current management strategies and service delivery in the longer term.

Professional dissemination:
1. A study report will be submitted to the funders and ethics committees
2. The Investigators will rapidly disseminate (oral presentation, email, social media) key findings to their clinical colleagues in the NHS and HEE in preparation for a full cRCT
3. The findings will be presented in an article that will be submitted to a high impact open access journal, accessible to UK and international professionals, targeting Plos One
4. Findings will be presented at Physiotherapy UK, and WCPT to target physiotherapists nationally and internationally

Patient/user dissemination:
1. A lay summary of the report will be written for patients
2. All study participants will receive a copy of the lay summary of findings
3. The source of funding will be acknowledged in all dissemination. Dissemination of findings will ensure confidentiality to participants

Intention to publish date

01/01/2020

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2019	11/05/2020	Yes	No
Results article	results	17/03/2020	21/07/2020	Yes	No
HRA research summary			28/06/2023	No	No